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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,738	09/12/2003	Egisto Boschetti	035394-0245	4938

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EXAMINER

HAQ, SHAFIQUK

ART UNIT PAPER NUMBER

1641

DATE MAILED: 12/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/660,738	BOSCHETTI ET AL.	
	Examiner	Art Unit	
	Shafiqul Haq	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-81 is/are pending in the application.
- 4a) Of the above claim(s) 3,5,7-9,23,24,30,31,76 and 77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6,10-22,25-29,32,33,51-55,75 and 78-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/21/05, 3/18/05, 1/4/05 & 2/19/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to election/restriction

1. Applicants' response filed September 21, 2005 to election requirement in Office Action mailed April 28, 2005 is acknowledged and entered.
2. Applicants' election with traverse of Group I, Claims 1-33 and 51-55 filed September 21, 2005 is acknowledged. Applicants' traversal is on the grounds that the "claims can be examined together without undue burden and restriction is improper between groups I and II". This is not found persuasive because of the reasons of record on pages 2 in Office Action of March 10, 2005. In addition, the search for each of the distinct inventions of Groups I-V is not co-extensive particularly with regard to the literature search. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group.

With regard to species election, claims are generic to multiple patentably distinct species. As for example, organic materials of claim 4 such as cellulose, polyacrylates, polyacrylamide, divinylbenzene, styrene etc. comprises structurally diverse compounds, which do not possess a substantial common core and would require diverse search. Monocyclic, polycyclic, aromatic and heteroaromatic groups of claim 1 are distinct in chemical structure and have different reactivities. Similarly mercapto and amino containing groups and sulfonate and phosphonate groups are distinct structurally and with respect to chemical reactivities and different combination of these groups would generate a wide variety of compounds which

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would impose an undue burden on the examiner to examine all the possible compounds the could encompass.

Finally, with respect to restriction between group I and II, the condition for patentability is different in each case. A patentability determination for Invention I would require an assessment of the novelty and unobviousness of tubular member containing chromatographic column having polycyclic heteroaromatic mercapto containing compound while a patentability determination for invention II would require an assessment of the novelty and unobviousness of the biochip having polycyclic heteroaromatic mercapto containing compound independent of any recited method of use. Thus, it will be an undue burden to examine both the inventive Groups in one application.

With respect to "how alleged species group J relates to alleged invention group I and II", this is just a typo and the correct sentence would be "If group I and II is elected, ONE species from each of the species groups A-H must be elected". Group J (claim 50) is related to group IV, and it is understandable the species of group J would be considered only if group IV is elected.

Accordingly, Claims 32-53 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Examiner suggests that the non-elected claims cited supra be canceled in response to this Office action to expedite prosecution.

Therefore, the restriction requirement is deemed appropriate and is made **FINAL**.

Claims status

3. Newly added dependent claims 75-81 are considered.
4. Claims 1-33 and 51-55 are elected.
5. Claims 3, 5, 7-9, 23-24, 30-31 and new claims 76 and 77 are directed to non-elected species and therefore, are withdrawn from consideration.
6. Claims 1-2, 4, 6, 10-22, 25-29, 32-33, 51-55, 75 and 78-81 are examined on merits.

Claim Objections

7. Claims 22 is objected to because of the following informalities: claim 22 refers to "group (c)", which is not correct. Group (c) is a linking group, not the compound as shown in the claim. Appropriate correction is required.
8. NPL documents cited in IDS filed 2/19/04 have not been considered because copies of those documents were not provided. In order to be in compliance with MPEP 609, III, A (2), applicants must provide copies of all of the references cited in the IDS. These references will become part of the official file of this application. Upon receipt of the missing documents, they will be considered by the examiner when preparing the next office action and a signed copy of form PTO-1449 will be provided with the next office action.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1-2, 4, 6, 10-15, 17-22, 25, 27-29, 32, 75, 78 and 80-81 are rejected under 35 U.S.C. 102(b) as being anticipated by Inoue et al. (US 5,700,630)

Inoue et al. disclose a solid substrate comprising a solid support, a polycyclic group that is heteroaromatic and that is substituted with sulfonate, a linking group comprising a mercapto that links the polycyclic heteroaromatic group to solid support (see abstract and formula (II); column 3, lines 28-30, 50-60 and specific examples of formula (II) in columns 16 and 21 specifically compounds (1), (2) and (47) to (49)).

As for claims 2 and 4, Inoue disclose solid support selected from group consisting of cellulose (column 24, lines 25-38).

As for claims 11-15, 17-22, 25, 27-29, 32, 75 and 80-81 Inoue disclose heteroaromatic compounds comprises mercapto containing moiety having at least one N, at least one S or at least two N atoms (compounds 1 and 2 of column 16 and compounds 47-49 of column 21).

Therefore, the reference is deemed to anticipate the cited claims.

11. Claims 1, 6, 10-22, 25, 27-28, 32, 75, 78 and 80-81 are rejected under 35 U.S.C. 102(b) as being anticipated by Osker Riester et al. (US 3305362).

Riester et al. disclose a solid substrate comprising a solid support (silver halide emulsion on a photographic film), a polycyclic group that is heteroaromatic and that

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is substituted with sulfonate and a linking group comprising a mercapto (see claims 1-21)

As for claims 11-15, 17-22, 25, 27-28, 32, 75, 78 and 80-81 Osker Riester et al. disclose heteroaromatic compounds having mercapto containing moiety and comprising heteroatom chosen from N, O, and S (see compounds of columns 7-12).

Therefore, the reference is deemed to anticipate the cited claims.

12. Claims 1,2 ,4, 6, 10-15, 17-18, 20-22, 25-26, 75 and 78-81 are rejected under 35 U.S.C. 102(e) as being anticipated by Stipanovic et al. (US 6,572,767 B2).

Stipanovic et al. disclose a solid substrate comprising a solid support, a polycyclic group that is heteroaromatic and that is substituted with sulfonate and a linking group comprising a mercapto (see abstract; column 9, lines 66-67; column 10, lines 15-67 and column 11, lines 1-55). The compound "2-mercapto-5-benzimidazolesulfonic acid" (column 10, line 67) anticipates the polycyclic heteroaromatic compound containing mercapto containing moiety with substituted sulfonate group of the present application.

Stipanovic et al disclose solid support comprising cellulose (column 11, lines 48-49). The mercapto containing compound (2-mercapto-5-benz-imidazolesulfonic acid) when reacted with epoxide functionalized moiety on solid support, furnish linkers of claims 26 and 33 (see reaction 5 of column 11).

Therefore, the reference is deemed to anticipate the cited claims.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 26, 33 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over a) each of Inoue et al. (US 5,700,630) and Osker Riester et al. (US 3305362) in view of b) Virtanen (US 2002/0014306A1), Schwarz et al (WO 95/31279) and the admitted prior art as set forth at page 16, paragraph [0047] of the specification.

Inoue et al. and Osker Riester et al. disclose a solid substrate comprising a solid support, a polycyclic group that is heteroaromatic and that is substituted with sulfonate and a linking group comprising mercapto containing moiety as described above in paragraphs 10 and 11.

Inoue et al. and Riester et al., however, do not disclose mercapto containing moiety as claimed in claims 26, 33 and 79.

Virtanen discloses mercapto-polyethylene glycol linker epoxide functionalized support (paragraph [0094]).

Swartz et al disclose heterocyclic mercapto containing ligand to link to solid support functionalized with epoxide (page 12, lines 9-13 and examples 1, 4, 5 and 7 of pages 15-19)

Admitted prior art disclose (paragraph [0047] of specification) that it is well-known chemistry that a "solid support that are functionalized with epoxides may undergo

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reaction with the mercapto to furnish a substrate with mercapto ethylene containing linking groups”.

Therefore, given the fact that epoxide functionized support is common and known in the art (Virtanen and Swatz) and the fact that reaction with mercapto containing moiety with epoxide furnish a substrate with mercapto ethylene containing linking group, one of ordinary skill in the art would expect to have similar linking group when mercapto containing polycyclic heteroaromatic compounds of Inoue et al. and Riester et al, link to a surface functionalized with epoxides.

15. Claims 51-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of 1) Stipanovic et al. (US 6,572,767 B2) and Schwarz et al (WO 95/31279), in view of 2) Horsman et al. (US 6,783,673 B2) and Andersen et al. (US 4,708,782).

Stipanovic et al. disclose a solid substrate comprising a solid support, a polycyclic group that is heteroaromatic and that is substituted with sulfonate and a linking group comprising a mercapto as described above in paragraph 12.

Schwarz et al disclose heterocyclic mercapto containing ligands for chromatographic separation of proteins (e.g. immunoglobulins) (see abstract; page 11, lines 7-10; page 12, lines 9-13) using solid support materials such as cellulose (page 11, lines 14-20).

Both Stipanovic et al and Schwarz et al disclose cellulose beads having heterocyclic mercapto containing compounds for chromatographic separation/purification of proteins (e.g. immunoglobulin). Although Stipanovic et al and Schwarz et al disclose batch chromatography (see example 7 of column 13 of

Stipanovic et al) and pseudoaffinity chromatography (see abstract of Schwarz et al) for separation, but fail to disclose chromatographic column having embodiments such as tubular membrane, porous members as claimed in claim 51.

Horsman et al disclose chromatography column comprising a tubular member having an inlet and an outlet, first and second porous members disposed within said tubular member and separating media packed within said tubular member between the first and the second porous members (see abstract; column 2 lines 16-65). The chromatography column can be connected to fluid control device for flowing a liquid sample (column 12, lines 47-52 and column 14, lines 29-38). Horsman et al also disclose that this composite chromatographic column have advantage over other chromatographic columns due to its improved axial compression of the media and low coefficient of friction.

Therefore, given the above fact that heterocyclic mercapto containing compounds bound to solid support (e.g. beads) are used for chromatographic separation of proteins and are used in different chromatographic embodiments (Stipanovic et al. and Schwarz et al) and the fact that column containing tubular member and porous members (Horsman et al) have certain advantage over other chromatographic columns, it would have been obvious at the time of the invention to a person of ordinary skill in the art to substitute a chromatographic columns of Stipanovic et al. and Schwarz et al, with equivalent column of Horsman et al, with the expectation similarly purifying/separating of proteins and immunoglobulins.

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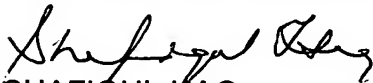
The features of the dependent claims (column volume 1ul to 5000 liters) constitute obvious variations in parameters which are routinely modified in the art depending on the sample volume.


Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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11/23/05